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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,782	07/03/2003	Patrizio Mattei	21159	6985
151	7590	04/06/2006	EXAMINER	
HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,782	Applicant(s) MATTEI ET AL.	
	Examiner Tamthom N. Truong	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,8,10-12 and 14 is/are rejected.
- 7) ☒ Claim(s) 2,3,7,13 and 15-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment of 03-03-06 has been fully considered.

- The deletion of the limitation of "*R⁵ and R⁶ together with the N atom to which they are attached form a 5 to 10 membered...heterocyclic ring...*" has overcome the previous 103 rejection based on **Breu et. al.** (WO'488).
- Thus, the previous 103 rejection is withdrawn herein.

Claims 6 and 9 are cancelled.

Claims 1-5, 7, 8 and 10-18 are pending.

An update search yields a new reference which necessitates new ground of rejection.

Therefore, the **finality of the previous action is withdrawn** herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 4, 5, 8, 10-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ife et. al.** (US 5,064,833 or US'833). On column 24 of US'833, Example 38 discloses a compound called *2-(2-methylphenylamino)-4-piperidinoquinazoline hydrochloride*. The disclosed compound is similar to the claimed formula I having A as a 6-membered heterocyclic ring. Said compound differs from the closest claimed compound by being unsubstituted vs. the claimed variable R¹, and by having a substituted amino at the 2-position (corresponding to R²). However, Ife et. al. teaches H as well as other groups can be present on the benzo portion of the quinazoline nucleus as can be seen in the definitions of R¹-R⁴ including *hydroxyl, alkoxy, amino* groups, and the definitions for R⁷ and R⁸ include *hydrogen, C₁₋₄alkyl, (CH₂)_nAr¹*. See column 1, lines 25-55.

The claimed ring A corresponds to the reference's -NR⁵R⁶ in which R⁵, R⁶ together with nitrogen can form a saturated or unsaturated heterocyclic ring.

The definition of the reference's R¹-R⁴ includes *hydrogen, amino, C₁₋₆alkylamino, diC₁₋₆alkylamino and hydroxyl*. Such an equivalent teaching would provide motivation to replace *hydrogen* with *amino, C₁₋₆alkylamino, diC₁₋₆alkylamino or hydroxyl*, which is a group represented by the claimed R¹ (or -O-R⁴, or -N(R⁵)(R⁶)).

As for the substituent at the 2-position, the disclosed generic formula (I) has $-NR^7R^8$ wherein R^7 and R^8 each represents *hydrogen*, *C₁₋₄alkyl*, *(CH₂)_nAr¹*. Thus, there is an equivalent teaching for an unsubstituted *amino* group and a substituted amino group.

Claim 12 is also rejected herein since pyrrolidine is clearly contemplated at the 4-position. See in particular claim 1.

The compounds are used to treat excessive gastric acid secretion. Thus, with the equivalent teaching provided, one would have been motivated to select compounds of the claimed formula I wherein:

- i. A is a heterocyclic ring including piperidino, pyrrolidino, etc. ;
- ii. R^1 is *hydroxy or amino*, and
- iii. R^2 is an *amino*.

Said compounds would have been expected to be able to treat excessive gastric acid secretion as well.

Therefore, at the time that the invention was made, it would have been obvious to select and make compounds of the claimed formula I in view of the teaching above.

Claim Objections

2. Claims 2, 3, 7, 13 and 15-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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- a. Claims 2 and 3 are directed to quinazoline compounds of formula I with R² as an alkyl (or methyl) group.
- b. Claims 7 and 13 are directed to quinazoline compounds of formula I with R⁴ as an aralkyl or a heterocyclalkyl group.
- c. Claims 15-18 are directed to a method of treating obesity, or a pharmaceutical composition comprising *orlistat*.

The prior art of record does not teach or fully suggested said compounds, method of treatment or pharmaceutical composition.

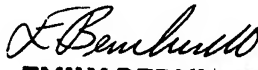
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tamthom N. Truong
Examiner
Art Unit 1624

3-31-06

 (for SPE)
EMILY BERNHARDT
PRIMARY EXAMINER
GROUP 1600
